

Application 10/061,036
Amendment Dated October 2, 2003
Response to Office Action mailed July 2, 2003

This listing of claims will replace all prior versions, and listings, of claims in the application:

A³

1. (Currently amended) A method for detecting the presence of at least one predesignated, target antibody to a ~~mycobacterium~~ Mycobacterium tuberculosis antigen in a sample selected from one or more patient bodily fluids, which comprises the following steps: (a) ~~contacting the sample of one or more patient bodily fluids with at least one mycobacterium antigen on a lateral flow assay membrane to bind to the target antibody in the sample~~ with a conjugated label having an indicator dye, thereby forming an antibody-conjugated label complex; (b) ~~previously, simultaneously or subsequently to step (a), binding the at least one mycobacterium antigen with a conjugated label~~ allowing the antibody-conjugated label complex to migrate along a lateral-flow assay membrane and contact at least one membrane-bound Mycobacterium tuberculosis antigen, thereby forming an antigen-antibody complex and causing the indicator dye to precipitate and form with a conjugated label producing a detectable signal; and (c) detecting the signal, whereby the presence of the target antibody is determined in the sample by the presence of the signal.

2. (Currently amended) The method of claim 1, wherein the one or more bodily fluids is selected from the group consisting of saliva, oral rinse expectorant, oral fluid, gingival crevicular fluid, urine, sweat, tears, blood, serum, stool, gastric fluid, synovial fluid, and phlegm, ~~culture media and other clinical and laboratory specimens and samples.~~

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3. (Original) The method of claim 1, wherein the one or more bodily fluids is saliva or diluted serum.

4. (Original) The method of claim 1, further comprising the step of evaluating immunization status of the patient from whom the sample came by comparing the signal or lack thereof with immunizations previously received by the patient and in comparison to a known standard control.

5. (Currently amended) The method of claim 1, wherein the ~~mycobacterium~~ antigen specifically binds to ~~mycobacterium tuberculosis~~ Mycobacterium tuberculosis specific antibodies.

6. (Currently amended) The method of claim 1, wherein the ~~at least one mycobacterium~~ antigen comprises a mixture two or more ~~mycobacterium~~ antigens.

7. (Currently amended) The method of claim 1, wherein the ~~at least one mycobacterium~~ antigen is selected from the group consisting of 38kDa and 16kDa antigens.

8. (Currently amended) The method of claim 1, wherein the membrane has at least a first stripe of the ~~at least one mycobacterium~~ antigen, and a control stripe, the

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control stripe formed by striping a material that will produce a detectable signal as the sample ~~react with sample antibodies as they flow~~s across the control stripe.

9. (Currently Amended) The method of claim 1, wherein the membrane has a least a first stripe of a first ~~at least one mycobacterium tuberculosis~~ antigen, a second stripe of a second ~~at least one mycobacterium~~ antigen that is different from the first mycobacterium tuberculosis antigen of the first stripe, and a control stripe, the control stripe formed by striping a material that will produce a detectable signal as the sample ~~react with sample antibodies as they flow~~s across the control stripe, the second stripe located between the first stripe and the control stripe.

10. (Original) The method of claim 9, wherein the second stripe comprises a shared mycobacterial antigen common to all mycobacteria or a mixture of such antigens.

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11. (Currently Amended) An immunoassay kit for detecting at least one predesignated target antibody to a ~~mycobacterium~~ Mycobacterium tuberculosis antigen in a sample selected from one or more patient bodily fluids which comprises: (a) a lateral-flow assay comprising a membrane sample pad, (b) a conjugated label pad, the conjugated label pad having an indicator dye, a portion of the conjugated label pad and a portion of the sample pad forming a first interface, and (c) a lateral-flow assay comprising a membrane, a portion of the membrane and a portion of the conjugated label pad forming a second interface, and (d) at least one ~~mycobacterium~~ Mycobacterium tuberculosis antigen bound to the membrane, the first interface allowing fluid to flow from the sample pad to the conjugated label pad and contact the indicator dye wherein the predesignated target antibody present in the sample forms a first complex with the conjugated label, the second interface allowing fluid to flow from the conjugated label pad to the membrane and to contact the at least one Mycobacterium tuberculosis antigen, the antigen forming a complex with the predesignated target antibody present in the sample and causing the indicator dye to precipitate and form a detectable signal.

12. (Currently Amended) The immunoassay kit of claim 11, wherein the at least one ~~mycobacterial~~ Mycobacterium tuberculosis antigen specifically binds to Mycobacterium tuberculosis specific antibodies.

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13. (Currently Amended) The immunoassay kit of claim 11, wherein the at least one ~~mycobacterium~~ Mycobacterium tuberculosis antigen comprises two or more ~~mycobacterial~~ Mycobacterium tuberculosis antigens.

14. (Currently Amended) The immunoassay kit of claim 11, wherein the at least one ~~mycobacterium~~ Mycobacterium tuberculosis antigen is selected from the group consisting of 38kDa and 16kDa antigens.

15. (Currently Amended) The immunoassay kit of claim 11, wherein the membrane has at least a first stripe of the at least one ~~mycobacterium~~ Mycobacterium tuberculosis antigen, and a control stripe, the control stripe formed by striping a material that will produce a detectable signal as the sample ~~react with sample antibodies as they~~ flows across the control stripe.

16. (Currently Amended) The immunoassay kit of claim 11, wherein the membrane has a least a first stripe of ~~at least one mycobacterium tuberculosis~~ a first antigen, a second stripe of ~~at least one mycobacterium~~ a second antigen that is different from the ~~mycobacterium tuberculosis~~ first antigen of the first stripe, and a control stripe, the control stripe formed by striping a material that will produce a detectable signal as the sample ~~react with sample antibodies as they~~ flows across the control stripe, the second stripe located between the first stripe and the control stripe.

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17. (Original) The immunoassay kit of claim 16, wherein the second stripe comprises a shared mycobacterial antigen common to all mycobacteria or a mixture of such antigens.

18. (Original) The immunoassay kit of claim 11, wherein the conjugated label pad comprises Protein A conjugated to a label.

19. (Currently amended) The immunoassay kit of claim 18, wherein the conjugated label is comprises colloidal gold.

20. (New) The method of claim 1, wherein the conjugated label comprises Protein A.

21. (New) The method of claim 20, wherein the conjugated label comprises colloidal gold.

22. (New) The method of claim 1, wherein the at least one membrane-bound *Mycobacterium tuberculosis* antigen is selected from the group consisting of purified protein derivative, natural and recombinant proteins selected from the group consisting of 38kDa, 16kDa, ESAT-6, MPT-63, TB23 HYT6, F29.47, 21-2H3, and MPT40 antigens or a mixture thereof.

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23. (New) The method of claim 9, wherein the first stripe comprises a latent *Mycobacterium tuberculosis* antigen, and the second stripe comprises an active *Mycobacterium tuberculosis* antigen.

24. (New) The method of claim 10, wherein the second stripe comprises a mixture of shared common mycobacterial antigens selected from the group consisting of P32 of *M. bovis*, 65kDa BCG antigen, 64kDa BCG antigen, MPB57, BCG-a, and LAM.

25. (New) The method of claim 1, wherein the antigen is a recombinant antigen.

26. (New) The immunoassay kit of claim 11, wherein the at least one *Mycobacterium tuberculosis* antigen bound to the membrane is selected from the group consisting of purified protein derivative, natural and recombinant proteins selected from the group consisting of 38kDa, 16kDa, ESAT-6, MPT-63, TB23 HYT6, F29.47, 21-2H3, and MPT40 antigens or a mixture thereof.

27. (New) The immunoassay kit of claim 16, wherein the first stripe comprises a latent *Mycobacterium tuberculosis* antigen, and the second stripe comprises an active *Mycobacterium tuberculosis* antigen.

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28. (New) The immunoassay kit of claim 17, wherein the second stripe comprises a mixture of shared common mycobacterial antigens selected from the group consisting of P32 of *M. bovis*, 65kDa BCG antigen, 64kDa BCG antigen, MPB57, BCG-a, and LAM.

29. (New) The immunoassay kit of claim 11, wherein the antigen is a recombinant antigen.